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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/521,696

03/09/00

KEITH

J

GI-5345

EXAMINER

HM22/0524

SEHARASEYON, J

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

05/24/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/521,696

Applicant(s)

KEITH ET AL.

Examiner

Jegatheesan Seharaseyon

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. The request filed on 5/10/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/521,696 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1-9 are pending and are rejected.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because the filing date for the previous provisional application (60/124,024) is not stated in the declaration.

Drawings

4. The drawings are objected to by the draftsman (Please see attached PTO948).
Correction is required.

Specification

5. The first line of the specification must contain references to the priority documents.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 4 is vague and indefinite for reciting the term "ng" quantity, because there is no reference to "ng" quantities in the specification on page 11. The specification only refers to "ug" quantities.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claim 1 is rejected under 35 U.S.C. 102 (a) as being anticipated by Hill et al. (1998).

The instant invention is directed to preventing an immune-mediated disorder by administering to a mammal, prior to tissue transplantation, a therapeutically effective amount of interleukin-11.

Hill et al. teaches the administration of interleukin-11 (IL-11) prior to tissue transplantation to prevent acute graft-versus-host disease, which is an immune-mediated disorder (see abstract). Therefore, Hill et al. teaches all the limitations of the instant claim 1.

7b. Claim 6 is rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (U.S. Patent No. 5,700,664).

The instant invention is directed to treating an immune-mediated disorder by administering to a mammal experiencing said immune-mediated disorder a therapeutically effective amount of interleukin-11.

Yang et al. teaches the use of interleukin-11 in a method of treating an immune-mediated disorder (column 11, lines 62-67) comprising administering to a subject a therapeutically effective amount of IL-11. Therefore, the disclosure of Yang et al. anticipates instant claim 6.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 1-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. (1998), in view of Yang et al. (U.S. Patent No. 5,700,664).

The instant invention is directed to the use of IL-11 to prevent immune mediated cytotoxicity.

The disclosure of Hill et al has been set forth above in paragraph 7a. However, Hill et al. does not disclose a daily dose of 1-100 micrograms/kg body weight.

Yang et al. discloses the administration of interleukin-11 at a daily dosage of between 1 and 1000 micrograms per kilogram of body weight depending on the patient, the severity of infection, and other clinical factors as determined by the physician (column 12, lines 35-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the instant invention was made to modify the method disclosed in Hill et al., by administering an IL-11 dosage of 1 and 100 micrograms per kilogram of body weight as suggested by Yang et al. because the reference teaches the dosage regimen of between 1 and 1000 micrograms per kilogram of body weight depending on the patient, the severity of infection, and other clinical factors as determined by the physician.

With respect to claims 3 and 5, it would be expected the IL-11 daily dosage

regimen would be started at the time of tissue transplantation and for three days beginning on the day of the tissue transplant because the administration of IL-11 at the time of transplantation would provide the maximum effect over the immune-mediated disorders .

With respect to claims 8 and 9, it would be expected that there will be improvement and remission of the immune-mediated disorder after the daily administration of IL-11 because the prior art teaches that treatment with IL-11 prevents the immune-mediated disorders.

9. No claims are allowed.

10. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

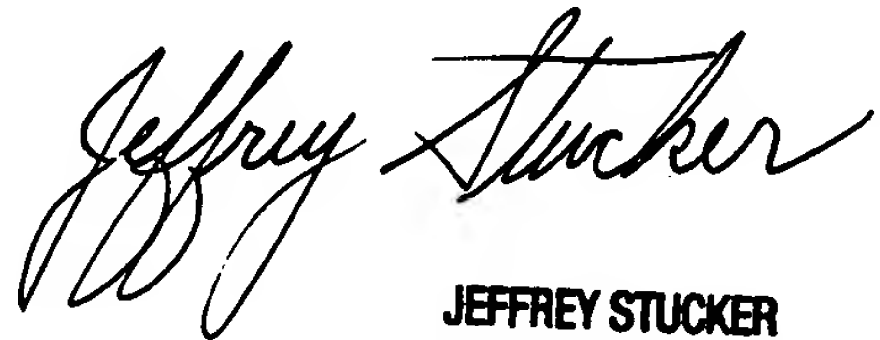
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
May 23, 2001



**JEFFREY STUCKER
PRIMARY EXAMINER**